

**REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office Action are respectfully requested in view of the following reasons.

***Rejections Under 35 U.S.C. §103***

Claims 1, 2, 6-8, and 12-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 6,443,883 issued to Ostrow et al. ("Ostrow") in view of U.S. Patent No. 6,464,986 issued to Aoki et al. ("Aoki"). Applicant respectfully traverses this rejection for at least the following reasons.

To establish an obviousness rejection under 35 U.S.C. § 103(a), four factual inquiries must be examined. The four factual inquiries include (a) determining the scope and contents of the prior art; (b) ascertaining the differences between the prior art and the claims in issue; (c) resolving the level of ordinary skill in the pertinent art; and (d) evaluating evidence of secondary consideration. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). In view of these four factors, the analysis supporting a rejection under 35 U.S.C. 103(a) should be made explicit, and should "identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, slip op. at 14-15 (2007). Furthermore, even if the prior art may be combined, there must be a reasonable expectation of success, and the reference or references, when combined, must disclose

or suggest all of the claim limitations. See *in re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In view of the above framework, Applicant respectfully submits that claim 1 is not obvious over Ostrow and Aoki for the reasons as follows:

First, there is no reason “that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements.” *KSR Int’l. Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, slip op. at 14-15 (2007). This is because, nevertheless both of Ostrow and Aoki teach a treatment of osteoporosis, each reference adopts a different way of the treatment, and therefore, there is no need to combine them to solve the same problem, i.e. the treatment of osteoporosis. Specifically, Ostrow discloses a PEMF biophysical stimulation field generator device and healing system using small coils 16 that creates a high magnetic flux penetration into tissues for treatment of a variety of conditions including osteoporosis (*See Ostrow*, Fig. 7) while Aoki teaches peripheral administration of a botulinum toxin to alleviate a non spasm pain due to, e.g. osteoporosis (*See Aoki*, Col. 24, lines 15-30). Here, each of the two references can solve the common problem *independently* and there was no “design need or market pressure” at the time the subject matter was made that led to combining the references. Thus, there is no reason for one of ordinary skill in the art, who knew Ostrow, to consult Aoki for the treatment of osteoporosis, which could be achieved by *each* of the references. Accordingly, it was not obvious for a skilled artisan to combine the references at the time the subject matter was made.

In contrast, the inventor of the present subject matter recognized a synergic effect when the pulsed signal therapy (PST<sup>®</sup>) is used with Botulinum toxin. “In particular, the pulsed signal

therapy (PST®) is used together with Botulinum toxin, which is used as an adjuvant. An adjuvant is an agent administered either alone, or simultaneously with, or in combination with, the main therapy, to achieve some desired effect. Here the main therapy is PST®. This led to [a] an increase in bone density. *It was found that Botulinum toxin, employed as an adjuvant, synergistically interacted with PST® specific, pulsating electromagnetic signals, to further enhance its bone density, stimulating potential.*” (Specification, page 9, 5<sup>th</sup> Para.-page 10, 1<sup>st</sup> Para.; Emphasis Added).

Second, assuming *arguendo* that the references may be combined and a reasonable expectation of success exists, the combined references do not disclose or suggest all of the claim features. Claim 1 recites, *inter alia*:

exposing a patient to *electromagnetic signals* generated by pulsating, impulse-modulated direct current, *having a frequency of 1 to 30 Hz and a field strength of 1 to 20 G* (Emphasis Added)

Applicant respectfully submits that neither Ostrow nor Aoki discloses, teaches, or suggests at least these features of claim 1. The Office Action concludes that “[r]egarding claim 1, Ostrow teaches a method for treatment of osteoporosis comprising exposing a patient to electromagnetic signals generated by pulsating, impulse modulated direct current, where the frequency is 1 to 30 Hz and the field strength is 1 to 20 G [co. 18, ll. 16-18, 29-31].” Applicant disagrees because Ostrow does not teach that the frequency of *the electromagnetic signals* is between 1 and 30 Hz, as required by claim 1. Rather, Ostrow discloses that “a low frequency component defining a square waveform treatment frequency of 25 pulses/sec, each having a

duration of 0.020 sec.” (Ostrow, Col. 18, lines 16-18). Here, the “low frequency component” is a component of the activation signal, which is produced by the controller 35 and applied to electromagnetic coils 16 (Ostrow, Col. 1, line 61-Col. 2, line 18; Col. 13, lines 19-24; Fig. 4; Figs. 8A-8E). The electromagnetic coils 16 generate an electromagnetic field when the activation signal is applied to them (Ostrow, Col. 8, lines 30-31; Figs. 8A-8E). Thus, the electromagnetic field and activation signal disclosed in Ostrow correspond to the “electromagnetic signals” and “pulsating, impulse-modulated direct current” of claim 1, respectively. Ostrow teaches that the activation signal, which corresponds to the “direct current” recited in claim 1, has a component having frequency of 25 pulses/sec while claim 1 requires that the “electromagnetic signals” have a frequency of 1 to 30 HZ. Accordingly, Ostrow fails to teach or suggest at least the above-recited features of claim 1.

Because none of Ostrow and Aoki discloses such claim features, even the combined references do not disclose, teach, or suggest every claim feature. Thus, Applicant respectfully submits that claim 1 is not obvious over the references, whether taken alone or in combination. Claims 2, 6-8, and 12-18 depend from claim 1 and are allowable for at least this reason.

Claims 1, 3, 6, 7, 9, and 12-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent Application Publication No. 2004/0077921 applied for by Becker et al. (“Becker”) in view of Aoki. Applicant respectfully traverses this rejection for at least the following reasons.

Becker teaches a method for the treatment of physical and mental disorders with

electromagnetic therapy but does not teach a method for treatment of “osteoporosis.” Thus, Applicant disagrees with the Office Action’s conclusion that “[r]egarding claim 1, Becker teaches a method for treatment of osteoporosis.” (Office Action, page 4, line 7) Further, in Becker, there is no recognition that a bone density could be increased using electromagnetic signals, as in the subject matter. In contrast to Becker, Aoki teaches a treatment of osteoporosis.

A skilled artisan would not have turned to Becker in order to seek further improvement over Aoki’s teachings on the osteoporosis treatment. Accordingly, there is no reason “that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements.”

*KSR Int’l. Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, slip op. at 14-15 (2007).

Furthermore, contrary to the Office Action’s conclusion in page 4, lines 7-9, Becker fails to disclose, teach, or suggest the features of claim 1, “exposing a patient to *electromagnetic signals* generated by pulsating, impulse-modulated direct current, *having a frequency of 1 to 30 Hz and a field strength of 1 to 20 G*” (Emphasis Added) because Becker teaches that “said circuit being effective to produce *a pulsed DC output* having a frequency in the range of about 0 to 45 Hz” (Emphasis Added) and here the “pulsed DC output” corresponds to the “direct current” of claim 1, NOT the “electromagnetic signals.” Thus, Becker does not teach or suggest at least the above-recited features of claim 1.

Because none of Becker and Aoki discloses such claim features, even the combined references do not disclose, teach, or suggest every claim feature. Thus, Applicant respectfully submits that claim 1 is not obvious over the references, whether taken alone or in combination. Claims 3, 6, 7, 9, and 12-18 depend from claim 1 and are allowable for at least this reason.

Claims 1-5, 7-11, and 13-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over U.S. Patent No. 4,674,482 issued to Waltonen et al. (“Waltonen”) in view of Aoki. Applicant respectfully traverses this rejection for at least the following reasons.

Applicant respectfully submits that Waltonen shares similar deficiencies as Becker as noted above: i.e. not disclosing, teaching, or suggesting any recognition that a bone density could be increased using electromagnetic signals, as in the subject matter, and the features, “exposing a patient to *electromagnetic signals* generated by pulsating, impulse-modulated direct current, *having a frequency of 1 to 30 Hz and a field strength of 1 to 20 G*” (Emphasis Added). Thus, claim 1 is allowable over Waltonen and Aoki for at least the reasons noted above with regard to the rejection using the references, Becker and Aoki. Also, Claims 2-5, 7-11, and 13-18 depend from claim 1 and are allowable for at least this reason.

Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-18. Since none of the other prior art of record, whether taken alone or in any combination, discloses or suggests all the features of the claimed subject matter, Applicant respectfully submits that independent claim 1, and all the claims that depend therefrom, are allowable.

**CONCLUSION**

Applicant believes that a full and complete response has been made to the pending Office Action and respectfully submits that all of the stated grounds for rejection have been overcome or rendered moot. Accordingly, Applicant respectfully submits that all pending claims are allowable and that the application is in condition for allowance.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicant's undersigned representative at the number below to expedite prosecution.

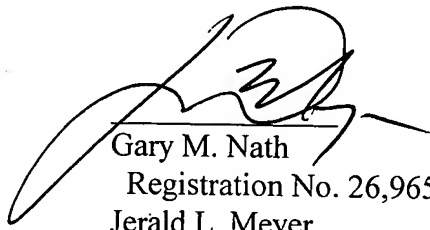
Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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